

headache. A high proportion of these can be attributed to overuse of analgesic drugs, female hormones, or a depressive state, and in 1988 it was far from clear how patients who improved after these aggravating factors had been corrected should be classified. The new revision attempts to address this problem by labelling such patients—for example, with both the original type of episodic headache, and also as “probable medication overuse headache”—and by allowing confirmation of this diagnosis only if the patient’s headache ceases to be chronic during a two month follow up period without regular analgesics. Patients with persistent headaches, defined as pain for more than 15 days a month for over three months, are then considered to be chronic.

In most patient based epidemiological studies about half these patients have previously had episodic migraine and the other half episodic tension type headache; only a very few patients have had de novo chronic headache, now to be called “new daily persistent headache.” As they become more chronic, headaches tend to have fewer features that unequivocally distinguish the tension type from migraine; Silberstein et al have argued cogently that to hang this distinction on the presence of “mild” or “moderate” nausea during the chronic phase is probably artificial, and that it is better to insist that migraine always takes precedence over other diagnoses in mixed headaches.³ Perhaps we should wait for physiological or therapeutic evidence that this distinction is of clinical relevance before we take this nicety too seriously.

In addition several headache syndromes have been characterised since 1988, most notably short lasting unilateral neuralgiform headache with conjunctival injection

and tearing or “SUNCT,” hypnic headache, hemicrania continua, and primary thunderclap headache, and these are now properly defined.⁴ Secondary (structural) causes of headache are clearly distinguished, and headache associated with psychiatric disease is placed in a category of its own for the first time.

This classification is certainly an improvement on the original, although it is still imperfect particularly in the eyes of neurologists seeing large numbers of “mixed pattern” headaches. Such a classification is essential for research, although clinicians must be aware that occasional patients fulfilling most of the criteria will have a more progressive disease. Many of the proposed fine distinctions seem relatively unimportant in routine neurological practice. If pathophysiological, genetic, or therapeutic evidence emerges it may prove necessary to revise the classification in a further decade or so, perhaps fragmenting the categories even further.

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Long term cognitive dysfunction in older people after non-cardiac surgery

Outcomes from various studies differ, and no definite conclusion is possible

Half of all people reaching the age of 65 subsequently have one or more operations,¹ but despite substantial research on short term cognitive dysfunction within the first week after the operation little research has been undertaken into the potential long term effects on cognition. The exception is cardiac surgery, where cognitive dysfunction has been well documented and has usually been attributed to the adverse effects of cardiopulmonary bypass on the brain.²⁻³ Various risk factors for long term (defined as three months or more) postoperative cognitive dysfunction have been investigated, including type of anaesthetic agent, general versus regional anaesthesia, use of anticholinergic agents such as atropine, or the physiological effects of the anaesthetic such as hypoxia, hypotension, or hyperventilation.

The multicentre International Study of Post-Operative Cognitive Dysfunction (ISPOCD1) compared 1218 patients aged 60 years and older undergoing major surgery with a control group (n = 321) of a similar age.⁴ At three months after the operation cognitive dysfunction was found in 9.9%

(94/1218) of patients compared with 2.8% (5/321) of controls. However, when a subset was re-tested one to two years later, 10.4% (35) showed cognitive dysfunction compared with 10.6% (5) of controls, which implies no long term effects, although the small control group (n = 47) may have been inadequate.⁵ No relation was found with hypoxaemia or hypotension, but a logistic regression analysis showed that higher age (P = 0.002), infectious complications in the post-operative period (P = 0.045), and cognitive dysfunction one week after surgery (P = 0.006), but not at three months, were significant risk factors for long term cognitive dysfunction one to two years after surgery.

Several studies involving patients who had undergone orthopaedic surgery have been carried out. Jones et al studied 146 patients aged over 60 years, who were randomly allocated to general anaesthesia or regional anaesthesia groups and compared with a control group of patients on the waiting list for surgery.⁶ The results showed no cognitive dysfunction after three months and no statistically significant differences between the groups.

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Williams-Russo et al conducted a randomised prospective study of epidural versus general anaesthesia on the incidence of long term cognitive dysfunction in 262 adults (134 receiving epidural anaesthesia, 128 general anaesthesia) aged over 40 years (mean age 69 years).⁷ At six months after surgery cognitive dysfunction was found in 6% (7) of the epidural group compared with 4% (5) in the general anaesthesia group.

Ancelin et al investigated the incidence of cognitive dysfunction in 140 people over the age of 64.⁸ At three months 56% (78) had notable deterioration of more than one standard deviation on one or more of the test scores. However, given the large number of cognitive tests used, the likelihood of type 2 errors occurring was increased. Those showing the greatest degree of deterioration tended to be the most elderly patients, those with the lowest educational level, and those with a history of cognitive decline before surgery. Nevertheless, both the Williams-Russo and the Ancelin studies did not include a control group comprising patients who had no surgery.

Several possible explanations exist for why such different outcomes have been seen. All the studies used different measures for cognitive assessment, and the measures used by Jones et al⁶ may be less sensitive to cognitive change than those used in the other studies. Also, the ISPOCD1 study found no difference between the control and surgery groups after one to two years.

Scant evidence exists about what may contribute to long term postoperative cognitive dysfunction even if it does exist. The two studies comparing general and epidural anaesthesia found no difference in outcome,^{6 7} and the ISPOCD1 study found no link between long term cognitive dysfunction and either hypoxaemia or hypotension.⁴ Four out of the five studies found that increasing age was a statistically significant risk factor in the development of long term postoperative cognitive dysfunction. However, higher age also increases the risk of developing dementia, emphasising the need for studies with adequate control groups. Other factors included a low educational level, a history of cognitive dysfunction before surgery, and cognitive dysfunction

at one week after surgery. Even so, most patients showing cognitive dysfunction after one week recovered after several months. The only indication of a possible preventive measure would be to reduce postoperative infection rates in surgical wards, and such measures are already standard practice.

Whether or not major surgery or general anaesthesia increases the risks of long term cognitive dysfunction remains unclear. The research so far has had methodological problems, and so it is not possible to draw conclusions. Future research needs to include validated, reliable, and sensitive cognitive assessments and well matched control groups to take into account the possible influences of disability, pain, and depression on cognitive function. Until such studies have been conducted and sufficient evidence is available it will be difficult to provide older patients with informed advice about the potential long term risks of surgery.

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Ethics review roulette: what can we learn?

That ethics review has costs and one size doesn't fit all

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Ethics review is an "intervention" in the system of health care that has been less evaluated than others. It aims to minimise risks to patients from inappropriate research or inadequate consent, but as a consequence it may delay or inhibit research beneficial to those same patients. The balance of risks and consequences will clearly be different for different types of research: some questionnaires, clinical audits, or comparisons of standard treatments are associated with low risks, while comparisons of known treatments against placebo and studies of new, potentially dangerous interventions carry higher risks.

To what extent might studies of variations in the work of research ethics committees help investigate how this balance is managed? In this week's *BMJ*, Hearnshaw reports the latest of several investigations documenting variations in the work of research ethics committees.¹ The principal messages from this body of evidence are that variations are often striking and the consequences can be substantial. In Hearnshaw's example, a trial of a leaflet intended to improve older patients' involvement in general practitioner consultations, was deemed not to require ethical review in Austria, France, Germany, and Switzerland. In the UK, Belgium, and Slovenia, however, the proposal had to

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